



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1051M]

Adjustment to the Aggregate Production Quota for Methylphenidate (for sale) for 2023

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Drug Enforcement Administration is adjusting the 2023 aggregate production quota for the schedule II controlled substance methylphenidate (for sale).

DATES: This final order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration, Telephone: (571) 776-3882.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas (APQ) for each basic class of controlled substance listed in schedule I and II. The Attorney General has delegated this function to the Administrator of the Drug Enforcement Administration (DEA) pursuant to 28 CFR 0.100.

Under 21 U.S.C. 826(h), when a request for individual manufacturing quota is submitted by a DEA-registered manufacturer pertaining to a schedule II controlled substance that is contained in a drug on FDA's list of drugs in shortage, DEA must complete review of such request not later than 30 days after receipt of the request. If,

after the review is completed, DEA finds it necessary to address a shortage of that controlled substance, DEA is to increase the aggregate and individual production quotas of that controlled substance and any ingredient therein to the level requested. 21 U.S.C. 826(h)(1)(B)(i). However, if it is determined that the level requested is not necessary to address the shortage, DEA is to provide a written response detailing the basis for the determination. 21 U.S.C. 826(h)(1)(B)(ii).

Background

DEA published the 2023 established APQ for controlled substances in schedules I and II in the *Federal Register* on December 2, 2022. 87 FR 74168. The 2023 established APQ represents those quantities of schedule I and II controlled substances that may be manufactured in the United States to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes. The final order stipulated that all APQ are subject to an adjustment, in accordance with 21 CFR 1303.15.¹

Quotas Applicable to Drugs in Shortage Pursuant to 21 U.S.C. 826(h)

DEA received written correspondence from FDA on August 10, 2023, in accordance with 21 U.S.C. 356c, addressing the domestic drug shortage of methylphenidate HCl extended-release tablets. In this letter, FDA advised DEA that on July 26, 2023, FDA added methylphenidate hydrochloride (HCl) extended-release tablets to its drug shortage list pursuant to 21 U.S.C. 356e. Under 21 U.S.C. 356c, manufacturers of drugs that are life-supporting, life-sustaining, or intended for the treatment or prevention of debilitating diseases or conditions must notify FDA of any

¹ Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2023, 87 FR 74168 (December 2, 2022).

permanent discontinuation or interruption in manufacturing likely to result in a meaningful disruption of the drug's supply in the United States. That provision further requires FDA to assess whether notifications received from manufacturers concern controlled substances subject to production quotas in accordance with 21 U.S.C. 826.

FDA's August 10th letter requested that DEA increase the APQ and individual manufacturing quotas for methylphenidate to a level that FDA deems necessary to address a shortage based on the best available market data.² On September 15, 2023, FDA clarified to DEA that methylphenidate is "intended for use in the prevention or treatment of a debilitating disease or condition" and therefore falls under the notification requirements of 21 U.S.C. 356c.

On September 14, 2023, DEA received a request for increased 2023 manufacturing quota pertaining to methylphenidate from a DEA registrant that is a manufacturer of that Schedule II controlled substance. Pursuant to this request, and following the receipt of the letter from FDA on August 10, DEA began its review under the timeframes specified by 21 U.S.C. 826(h)(1).

Analysis for the Adjustment to the 2023 Methylphenidate (for sale) Aggregate Production Quota

In conducting the review under 21 U.S.C. 826(h) in order to determine the necessity of this adjustment, the Administrator has considered the criteria in accordance with 21 CFR 1303.13 (adjustment of APQ for controlled substances). The Administrator is authorized to increase or reduce the aggregate production quota at any time. 21 CFR 1303.13(a). DEA regulations state that there are five factors that shall be considered in determining to adjust the aggregate production quota. 21 CFR 1303.13(b). Accordingly, the Administrator has taken into account the following factors described below for 2023:

² As the FDA's specific requested levels would reveal proprietary manufacturing data, DEA is not specifying the requested levels in this document.

(1) changes in the demand for that class, changes in the national rate of net disposal of the class, changes in the rate of net disposal of the class by registrants holding individual manufacturing quotas for that class, and changes in the extent of any diversion in the class; (2) whether any increased demand for that class, the national and/or individual rates of net disposal of that class are temporary, short term, or long term; (3) whether any increased demand for that class can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the aggregate production quota, taking into account production delays and the probability that other individual manufacturing quotas may be suspended pursuant to 21 CFR 1303.24(b); (4) whether any decreased demand for that class will result in excessive inventory accumulation by all persons registered to handle that class (including manufacturers, distributors, practitioners, importers, and exporters), notwithstanding the possibility that individual manufacturing quotas may be suspended pursuant to 21 CFR 1303.24(b) or abandoned pursuant to 21 CFR 1303.27; and (5) other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires. 21 CFR 1303.13(b).

DEA reviewed domestic data from the latest IQVIA report on stimulant prescribing that described a 9.1 percent increase in prescribing of methylphenidate HCl products from 2021 to 2022.³ However, FDA's estimate of domestic medical need for

³ Stimulant Prescription Trends in the United States from 2012-2022. IQVIA Government Solutions, Inc., August 31, 2023.

methylphenidate drug products predicted a 0.11 percent increase for 2023 domestic need when compared to 2022 observed need. DEA believes that manufacturers can easily meet this insignificant increase in domestic medical need with currently established quotas.

DEA also reviewed published reporting of methylphenidate production and consumption globally found in the INCB's *Psychotropic Technical Report for 2022*.⁴ This report outlines that U.S. production of methylphenidate accounted for 72.5 percent of global production and the U.S. was the leading exporter of methylphenidate in 2021. The number of countries and territories reporting the importation and consumption of methylphenidate drug products increased 5 percent and 8 percent, respectively, from 2020 to 2021. The report states that consumption rates in several European countries increased in 2021. Additionally, DEA reviewed export data extracted from DEA's internal databases and reported to the United Nations as part of the U.S.' treaty obligations for controlled substances. The export data showed that exports of drug products containing methylphenidate increased from 13,083kg in 2021 to 15,792kg in 2022. Extrapolation utilizing previous years' reported export data suggests a similar quantity of drug products containing methylphenidate HCl will be exported from the U.S. in 2023.

After considering these factors, DEA determined that it is necessary to increase the established 2023 APQ for the schedule II-controlled substance methylphenidate (for sale) to be manufactured in the United States to provide for the estimated needs of the United States and export requirements to meet global demand. This adjustment is necessary to ensure that the United States has an adequate and uninterrupted supply of methylphenidate (for sale) to meet legitimate patient needs both domestically and

⁴ INCB Psychotropics - Technical Report Psychotropic Substances 2022, Statistics for 2021, Assessments of Annual Medical Scientific Requirements for Substances for 2023.

globally.

Additional Legal Considerations

The procedures previously adopted by DEA for adjustment of APQ are set forth in DEA regulations in 21 CFR 1303.13. Under that provision, the Administrator, upon determining that an adjustment of the aggregate production quota of any basic class of controlled substance is necessary, shall publish in the Federal Register general notice of an adjustment in the aggregate production quota for that class. The regulation further directs that DEA will allow any interested person to file comments or objections to the adjusted APQ within the time specified by the Administrator in the notice. Section 1303.13 further provides that, “[a]fter consideration of any comments or objections . . . the Administrator shall issue and publish in the Federal Register his final order determining the aggregate production quota for the basic class of controlled substance.”

The statutory timeframe applicable to actions taken under 21 U.S.C. 826(h) was enacted by Congress after DEA established its regulations in 21 CFR 1303.13. DEA has determined that it is not possible to increase the APQ within the Congressionally-mandated 30-day period while also complying with the procedures that DEA previously had laid out in 21 CFR 1303.13. Therefore, the Administrator has determined that, in order to comply with the 30-day timeframe in 21 U.S.C. 826(h), this final order must be published without opportunity for comment and made effective immediately.

Determination of 2023 Adjusted Methylphenidate (for sale) Aggregate Production Quota

In determining the adjustment of the 2023 methylphenidate (for sale) aggregate production quota, DEA has taken into consideration the factors set forth in 21 CFR 1303.13(b) in accordance with 21 U.S.C. 826(a) as well as 826(h). Based on all of the above, the Administrator is adjusting the 2023 aggregate production quota for methylphenidate (for sale).

The Administrator hereby adjusts the 2023 APQ for the following schedule II-controlled substance expressed in grams of anhydrous acid or base, as follows:

Controlled Substance	Current APQ (g)	Adjusted APQ (g)
Schedule II		
Methylphenidate (for sale)	41,800,000	53,283,000

The APQ for all other schedule I and II controlled substances included in the 2023 established APQ remain at this time as previously established.

Signing Authority

This document of the Drug Enforcement Administration was signed on September 29, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Heather Achbach,
Federal Register Liaison Officer,
Drug Enforcement Administration.

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